

TRANSMITTAL LETTER TO THE UNITED STATES

VOL. 130

DESIGNATED/ELECTED OFFICE (DO/EO/US)

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

CONCERNING A FILING UNDER 35 U.S.C. 371

09/509595

INTERNATIONAL APPLICATION NO.

PCT/EP98/06294

INTERNATIONAL FILING DATE

October 2, 1998

PRIORITY DATE CLAIMED

October 2, 1997

TITLE OF INVENTION

NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)

APPLICANT(S) FOR DO/EO/US

LEENA PELTONEN; JOHANNA AALTONEN; PETRA BJORSES; JAAKKO PERHEENTUPA; AARNO PALOTIE; NINA HORELLI-KUITUNEN; MARIE-LAURE YASPO; HANS LEHRACH

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
 - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☒ has been transmitted by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
 - b. ☐ have been transmitted by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

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| | | |
|--|--|---|
| U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.53) 09/50959 | INTERNATIONAL APPLICATION NO. PCT/EP98/06294 | ATTORNEY'S DOCKET NUMBER VOSS1130 |
|--|--|---|

| | | | | | |
|---|---------------------|---------------------|-------------|----------------------------------|-----------|
| 21. The following fees are submitted: | | | | CALCULATIONS PTO USE ONLY | |
| BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) : | | | | | |
| <input type="checkbox"/> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO \$970.00 | | | | | |
| <input checked="" type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO \$840.00 | | | | | |
| <input type="checkbox"/> International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO \$690.00 | | | | | |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) \$670.00 | | | | | |
| <input type="checkbox"/> International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) \$96.00 | | | | | |
| ENTER APPROPRIATE BASIC FEE AMOUNT = | | | | \$840.00 | |
| Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input checked="" type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (e)). | | | | \$130.00 | |
| CLAIMS | NUMBER FILED | NUMBER EXTRA | RATE | | |
| Total claims | 42 - 20 = | 22 | x \$18.00 | \$396.00 | |
| Independent claims | 1 - 3 = | 0 | x \$78.00 | \$0.00 | |
| Multiple Dependent Claims (check if applicable). <input checked="" type="checkbox"/> | | | | \$260.00 | |
| TOTAL OF ABOVE CALCULATIONS = | | | | \$1,626.00 | |
| Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). <input checked="" type="checkbox"/> | | | | \$813.00 | |
| SUBTOTAL = | | | | \$813.00 | |
| Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). | | | | \$0.00 | |
| TOTAL NATIONAL FEE = | | | | \$813.00 | |
| Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). <input type="checkbox"/> | | | | \$0.00 | |
| TOTAL FEES ENCLOSED = | | | | \$813.00 | |
| | | | | Amount to be: refunded | \$ |
| | | | | charged | \$ |

☐ A check in the amount of _____ to cover the above fees is enclosed.

☒ Please charge my Deposit Account No. **07-1895** in the amount of **\$813.00** to cover the above fees.
A duplicate copy of this sheet is enclosed.


☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **07-1895** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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SIGNATURE

Lisa A. Haile
NAME

38,347
REGISTRATION NUMBER

28 March 2000
DATE

Attorney Docket No.: VOSS1130

Applicant: Leena Peltonen et al.

Serial No.: 09/509,595

Filed: March 28, 2000

Title: NOVEL NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
(37 C.F.R. §§1.9(f) and 1.27(d) - NONPROFIT ORGANIZATION)

I hereby declare that I am an official empowered to act on behalf of the nonprofit organization identified below:

NAME OF ORGANIZATION: **Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V.**
ADDRESS OF ORGANIZATION: **Berlin, GERMANY**

TYPE OF ORGANIZATION

- ☐ University or other Institution of Higher Education
☒ Tax Exempt under Internal Revenue Service Code (26 U.S.C. §§501(a) and 501(c) (3))
☐ Nonprofit Scientific or Educational under Statute of State of the United States of America (Name of State _____) (Citation of Statute _____)
☒ Would qualify as tax exempt under Internal Revenue Service Code (26 U.S.C. §§501(a) and 501(c) (3)) if located in the United States of America
☐ Would qualify as nonprofit Scientific or Educational under Statute of State of the United States of America if located in the United States of America (Name of State _____) (Citation of Statute _____)

I hereby declare that the nonprofit organization identified above qualifies as a nonprofit organization as defined in 37 C.F.R. §1.9(e) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, with regard to the invention entitled **NOVEL NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)** by inventors **Leena Peltonen; Johanna Aaltonen; Petra Björnses; Jaakko Perheentupa; Aarno Palotie; Nina Lorelli-Kuitunen; Marie-Laure Yaspo; Hans Lehrach** as described in

- ☐ the specification filed herewith
☒ application Serial No. 09/509,595 filed March 28, 2000
☐ Patent No. _____, issued _____

I authorize and request insertion of the serial number of the application when officially known.

I hereby declare that rights under contract or law have been conveyed to and remain with the nonprofit organization with regard to the above-identified invention.

If the rights held by the nonprofit organization are not exclusive, each individual, concern or organization having rights to the invention is listed below and no rights to the invention are held by any person, other than the inventor, who could not qualify as a small business concern under 37 C.F.R. §1.9(d) or by any concern which would not qualify as a small business concern under 37 C.F.R. §1.9(d) or a nonprofit organization under 37 C.F.R. §1.9(e).

NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 C.F.R. §1.27).

Full Name National Public Health Institute
Address Mannerheimintie 106, 00300 Helsinki, Finland
☐ Individual ☐ Small Business Concern ☒ Nonprofit Organization

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate (37 C.F.R. §1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF PERSON SIGNING Christa Herzog
TITLE IN ORGANIZATION Head of Patent Department
ADDRESS OF PERSON SIGNING Hofgartenstr. 8, 80539 Munchen, GERMANY
SIGNATURE Christa Herzog DATE 4 July 2000

09/509595

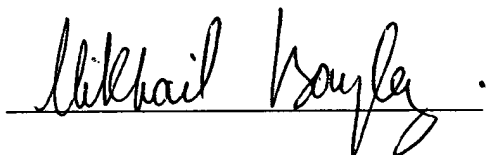
DOCUMENT: U.S. NATL PHASE APPLICATION
DOCKET NO.: VOSS1130
SERIAL NO.: UNASSIGNED

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DATE OF DEPOSIT March 28, 2000

I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 CFR 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS WASHINGTON, D.C. 20231.

Mikhail Bayley

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